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United States Senate

WASHINGTON, DC 20510

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The Honorable Norman Sharpless, M.D.
Acting Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Sharpless:

I am writing to express my concern about the potential for the application of the Food and Drug Administration's (FDA's) "orphan drug exclusivity" to result in significant delays in competition and options for newer forms of buprenorphine—a drug that is critical to medication-assisted treatment (MAT) for opioid use disorder. Opioid use disorder is not a rare disease; it is in the middle of an epidemic. Drugs used to treat opioid use disorder should not be entitled to market exclusivity benefits that are intended for rare disease drugs under the Orphan Drug Act.

The original brand name buprenorphine drug, "Subutex," was approved by FDA over 25 years ago and upon approval was awarded market exclusivity as an orphan drug, which shielded the drug from generic competition from 2002 to the end of 2009, for the first seven years that the drug was on the market. Yet now, the manufacturer of the drug is seeking an additional seven years of market exclusivity for "Sublocade," a new formulation of buprenorphine that is administered with a monthly injection. This monthly injection version could help to improve the administration of MAT and success of MAT for patients with opioid use disorder, as compared to versions of buprenorphine that require daily dosing. However, the product is priced at $1,580 per month by the drug manufacturer.[1] Providing the monthly injection version of buprenorphine with orphan drug exclusivity could lock-in these high prices for seven years or even longer.

Given the scope and severity of the opioid epidemic, the prevalence of opioid use disorder in New Hampshire and across the country and the billions of dollars in revenue that Subutex and Suboxone have already generated since 2002 for the products' manufacturer, the FDA should not allow the orphan drug approval process to be gamed by drug manufacturers seeking to limit competition and elevate the price of monthly buprenorphine injections.

Under the Orphan Drug Act, FDA may grant an Orphan Drug Designation, and the market exclusivity that accompanies that designation, if the drug is used to treat a condition that affects fewer than 200,000 American patients or in instances where the manufacturer of the drug is not expected to recover the costs of developing and marketing the drug (known as "cost recovery").

[1] Indivior PLC, "Sublocade Fact Sheet," Accessed September 5, 2019. Available at: http://indivior.com/wp-content/uploads/2017/11/SUBLOCADE-Fact-Sheet.pdf

In 1994, Subutex was granted an Orphan Drug Designation on the basis of the cost recovery criteria—because at the time it was anticipated that buprenorphine would only be used in methadone clinics, which would limit the number of patients that received buprenorphine and the ability of the manufacturer to recover development and marketing costs. However, following subsequent changes in law, buprenorphine was allowed to be furnished in outpatient settings, which greatly expanded the scope of patients who can receive buprenorphine. Therefore, it is highly unlikely that buprenorphine would meet either of the qualifications for an Orphan Drug Designation today.

At a time when prescription drug costs are stretching household budgets and the opioid epidemic is still devastating communities across the country, I am concerned that granting orphan drug exclusivity for Sublocade could put access to promising developments in MAT out of reach for patients with opioid use disorder and limit treatment options. The circumstances in the case of Sublocade also raise broader questions about Orphan Drug Designations. To help address these concerns, I request answers to the following questions:

1. Does FDA have any processes for measuring whether drugs that obtain Orphan Drug Designations based on the "cost recovery" criteria ultimately achieve substantial sales revenue?

2. Are there revisions to the Orphan Drug Act that Congress could establish to help ensure that orphan drugs that meet the "cost recovery" criteria at the time of designation are not entitled to later obtain additional Orphan Drug Designations if the drug has already achieved significant sales revenue?

I appreciate your ongoing commitment to ensuring that communities across the country have access to affordable options for treatment of opioid use disorder. Your attention to this issue will help ensure that patients are not barred from accessing new and effective forms of opioid use disorder treatment due to the high cost of the drugs. Should your staff have any questions regarding this inquiry, please do not hesitate to contact [redacted].

Sincerely,

Jeanne Shaheen
United States Senator